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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/731,723	12/09/2003	Lee D. Jennings	AM100635	5557
25291	7590	09/20/2004	EXAMINER	
WYETH PATENT LAW GROUP 5 GIRALDA FARMS MADISON, NJ 07940			SHAMEEM, GOLAM M	
			ART UNIT	PAPER NUMBER
			1626	

DATE MAILED: 09/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/731,723

Applicant(s)

JENNINGS, LEE D.

Examiner

Golam M M Shameem

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 August 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 6 and 8-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Priority

This application claims benefit for domestic priority under 35 U.S.C. § 119(e) (to a provisional application 60/432,107 12/10/2002), is acknowledged.

Status of Claims

Claims 1-20 are currently pending in the application.

Claims 6, and 8-20 are withdrawn from further consideration pursuant to 37 C.F.R. 1.142 (b) as being drawn to a non-elected subject matter.

Information Disclosure Statement

Receipt is acknowledged of Information Disclosure Statement (IDS), filed on 03/03/2004, which has been entered in the file.

Response to Election/Restriction

In response to the restriction requirement, Applicants have elected Group I, which includes claims 1-5 and 7 drawn to a compound and composition of formula (I), and elected the species found in Example 1, on page 20 with traverse is acknowledged. The traversal is on the ground(s) that all the pending claims should be rejoined and examined with the elected Group I because a search and examination of the entire application can be made without "a serious burden" on the Examiner.

The Examiner respectfully disagrees with the Applicants because the products of Invention groups I-III differ materially in structure and in element from each other and therefore, are capable of supporting their own patents. The invention groups I-III are related to a set of structurally diverse compounds, and their methods of use (chemical structures, which are similar,

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are presumed to function similarly, whereas chemical structures that are not similar are not presumed to function similarly), which do not possess a substantial common core wherein a reference anticipating one would not necessarily render the other obvious and to search all the above groups in a single application would be an undue burden on the Examiner. Because of the plethora of classes and subclasses in each of the Group, a separate search considerations are involved, which would impose a serious burden on the Examiner to perform a complete search of the defined areas if unrestricted. Also the fields of search are not coextensive. The wide disparity among the groups requires that many divergent fields must be searched, including all classes and subclasses of U.S. and foreign patents as well as journals and publications. Moreover, the Examiner must perform a commercial database search on the subject matter of each group in addition to a paper search, which is quite burdensome to the Examiner. However, Examiner may reconsider to rejoin method of use claims commensurate in scope with the product claims when the case would be found in condition for allowance [provided those method claims are free from 35 U.S.C. §112 first (including written description, reach-through claim language and/or scope-enablement issues) and second paragraphs]. For these reasons, Applicant's arguments are found unpersuasive and, therefore, the requirement for restriction and election of species is still deemed proper and is therefore made FINAL.

Applicants preserve their right to file a divisional on the non-elected subject matter.

As set forth in the restriction requirement and an election of a single compound (or set of compounds), the invention will encompass all compounds that fall within the scope of the claim is as follows:

A compound having the formula (I) wherein:

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R₁ is as claimed except "hydrogen, C₂-C₆ alkyl",

R₂ is as claimed except any further heterocyclic ring substitutions such as "thienyl, furanyl" etc,

R₃ is as claimed except "hydrogen, C₁-C₆ alkyl, C₂-C₆ alkoxy",

R₄ is as claimed except "C₁-C₃ alkoxy" and any further heterocyclic ring substitutions such as "thienyl, furanyl" etc, and

R₅ is as claimed except "C₁-C₈ alkyl" and any further heterocyclic ring substitutions such as "pyridinyl, thienyl, furanyl" etc.

As a result of the election and the corresponding scope of the compound identified, claims 6, and 8-20 and the remaining subject matter of claims 1-5 and 7 are withdrawn from further consideration pursuant to 37 CFR 1.142 (b) as being drawn to non-elected inventions. The withdrawn subject matter of claims 6, and 8-20 is properly restricted as it differs materially in structure and in element from the elected subject matter supra so as to be patentably distinct there from.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a), which forms the basis for all obviousness rejections, set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hercelin *et al* (1984) and further in view of Bell M. R. (1970).

Applicant claims the substituted indole acetic acid derivatives of formula (I) that are useful as plasminogen activator inhibitor-1 and pharmaceutical compositions thereof.

Determination of the scope and content of the prior art (MPEP §2141.01)

Hercelin *et al* and Bell *et al* independently teach the analogous substituted indole compounds to those instantly claimed invention.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the instantly claimed compounds and that of the reference herein lies in the selection of different variables (such as R₁, R₂ and R₃ etc) in core indole ring of formula (I), wherein R₁ is hydrogen in indole ring of the instantly claimed compound (wherein R₂ is hydrogen atom, R₃ is hydrogen or alkoxy, R₄ is alkoxy, R₅ is halogen substituted phenyl) instead of alkyl (Me) for the same position of R₁ in the prior art (RN 25803-14-9, and also see RN 26211-72-3, RN 26296-60-6, CAPLUS database, a copy is provided herewith).

Finding of prima facie obviousness--rational and motivation (MPEP §2142-2413)

It is well established that the substitution of hydrogen for alkyl on a known compound is not a patentable modification absent unexpected or unobvious results. *In re Wood*, 199 U.S.P.Q. 137 (C.C.P.A. 1978) and *In re Lohr*, 137 U.S.P.Q. 548, 549 (C.C.P.A. 1963). The claimed compounds are so closely related structurally to the homologous compounds of the reference as to be structurally obvious therefore in the absence of any unobviousness or unexpected properties. Therefore, in the instant case, one skilled in the art would be motivated to choose to replace a hydrogen atom for a methyl group or vice versa in view of the known teaching of the art. Since the core indole ring of formula (I) is not novel and the novelty (if there is any) lies in the selection of different variable substitutions, a great caution should be exercised to determine the patentability of the claimed invention. Therefore, in looking at the instant claimed

compounds as a whole, the claimed compounds would have been suggested to one skilled in the art unless unobvious or unexpected results can be shown.

Objections

Claims 1-5 and 7 are objected to for containing non-elected subject matter. The claims should be amended to exclude non-elected subject matter and within the scope of elected compound.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Golam Shameem, Ph.D. whose telephone number is (571) 272-0706. The examiner can normally be reached on Monday-Thursday from 6:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane, can be reached at (571) 272-0699. The Unofficial fax phone number for this Group is (703) 308-7921. The Official fax phone numbers for this Group are (703) 308-4556 or 305-3592.

When filing a FAX in Technology Center 1600, please indicate in the Header (upper right) "Official" for papers that are to be entered into the file, and "Unofficial" for draft documents and other communications with the PTO that are not for entry into the file of the application. This will expedite processing of your papers.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [joseph.mckane@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees will not communicate with applicant via Internet

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e-mail where sensitive data will be exchanged or where there exists a possibility that sensitive data could be identified unless there is of record an express waiver of the confidentiality requirements under 35 U.S.C. 122 by the applicant. See the Interim Internet Usage Policy published by the Patent and Trademark Office Official Gazette on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (571) 272-1600.

A handwritten signature in black ink, appearing to read "Golam M M Shameem". The signature is stylized with a large, looping initial "G" and "M".

Golam M M Shameem, Ph.D.
Patent Examiner
Art Unit 1626, Group 1600
Technology Center 1

September 15, 2004